FINAL STATEMENT OF REASONS FOR RULEMAKING

STAFF REPORT/EXECUTIVE SUMMARY

PROPOSED IDENTIFICATION OF INORGANIC LEAD AS A TOXIC AIR CONTAMINANT

Prepared by the Staff of
the Air Resources Board and
the Office of Environmental Health Hazard Assessment

As approved by the Air Resources Board on:
April 24, 1997

In accordance with California Health and Safety Code sections 39660-39662, the Air Resources Board staff is recommending that the Board consider the identification of inorganic lead as a toxic air contaminant. The draft report, Proposed Identification of Inorganic Lead as a Toxic Air Contaminant, was written and revised numerous times as a result of public comments received during several public comment periods, and public workshops conducted on April 21, 1993, May 20, 1994, and March 7, 1996. This current version is being made available to the public for a seventh comment period. No control measures are being proposed in this report. The Scientific Review Panel has approved the report and prepared Findings which are included in the Staff Report/Executive Summary. The report will be presented to the Air Resources Board at a public hearing on April 24, 1997. If the Air Resources Board approves the report and identifies inorganic lead as a toxic air contaminant, the information in the report may become part of an evaluation to determine the potential need for and the development of control measures. Any consideration of potential control measures will be conducted through a full public participatory process, including public comment periods and workshops. In preparing this report, we reviewed pertinent literature through May 1996.

Preface*

The Air Resources Board (ARB) has reviewed the Staff Report and the Scientific Review Panel's (SRP) Findings in the matter of the *Proposed Identification of Inorganic Lead as a Toxic Air Contaminant*. On this review, the ARB acknowledges and agrees with the SRP and the ARB and Office of Environmental Health Hazard Assessment staff that uncertainty exists when dealing with the quantitative correlation of potential health effects (neurodevelopmental effects in children, cardiovascular effects in adults, and potential carcinogenicity) at exposure to low levels of air concentrations of inorganic lead.** The information contained in this report form the basis for the identification of inorganic lead as a Toxic Air Contaminant. No controls or risk management decisions are made in this report. As risk management guidelines are developed, the uncertainties will be taken into account and the science updated as appropriate.

Further, given the complexity of the models and the limitations of interpretation of the tests of Intelligence Quotient (IQ) used to correlate the neurodevelopmental effects to low air concentrations of air lead, the reader needs to be aware that the fractional (IQ) measurements related to the low statewide ambient air lead concentrations are given as an example of directional effects and involves uncertainty and should not be viewed as definitive.

This preface is not intended in any way to modify the SRP's Findings on the inorganic lead report. In addition, this preface was not reviewed or accepted by the SRP.

* Added by the Air Resources Board at its April 24, 1997 hearing in response to public comment.

** Low levels of air concentrations of inorganic lead means average ambient air measurements. The statewide population-weighted average is estimated to be 0.02 micrograms per cubic meter based on data collected in 1994-95.

INITIAL STATEMENT OF REASONS FOR RULEMAKING

STAFF REPORT/EXECUTIVE SUMMARY

What is the Initial Statement of Reasons for Rulemaking?

This report is a summary of the information used by the members of the Air Resources Board (ARB or Board) to determine if inorganic lead should be listed as a toxic air contaminant (TAC). The Board will consider the identification of inorganic lead as a TAC at a public hearing in April 1997, in accordance with California Health and Safety Code section 39662.

What is Contained in the Initial Statement of Reasons for Rulemaking?

The Initial Statement of Reasons for Rulemaking for the Proposed Identification of Inorganic Lead as a TAC consists of a Staff Report/Executive Summary (which summarizes the scientific basis for the proposed regulation), a discussion of the environmental and economic impacts of the proposal, the Findings of the Scientific Review Panel (SRP), and the Proposed Regulation Order.

What is Contained in This Report?

This report consists of a Staff Report/Executive Summary which summarizes the scientific basis for the proposed regulation to identify inorganic lead as a TAC, and Parts A, B, and C of the Technical Support Document. Inorganic lead consists of lead compounds that do not contain carbon and includes metallic or elemental lead. Part A, prepared by the ARB staff, is an evaluation of emissions of inorganic lead, ambient and indoor concentrations, statewide population exposure, and atmospheric persistence and fate. Part B, prepared by the Office of

Environmental Health Hazard Assessment (OEHHA) staff, assesses the health effects of inorganic lead. Part C consists of copies of the public comments received on the previous draft versions of the report, and the ARB/OEHHA staff responses.

What is a Toxic Air Contaminant (TAC)?

According to section 39655 of the California Health and Safety Code, a toxic air contaminant is "an air pollutant which may cause or contribute to an increase in mortality or an increase in serious illness, or which may pose a present or potential hazard to human health." In addition, substances which have been listed as federal hazardous air pollutants (HAPs) pursuant to section 7412 of Title 42 of the United States Code are TACs under the state's air toxics program pursuant to section 39657 (b) of the California Health and Safety Code. The Board formally made this identification on April 8, 1993 (Title 17, California Code of Regulations, section 93001).

Lead compounds (which include organic and inorganic lead compounds) are listed as HAPs and, therefore, were identified as TACs on April 8, 1993. However, the federal HAPs list does not include elemental lead in the definition of lead compounds. Elemental lead is included in the ARB/OEHHA definition of inorganic lead and is therefore being considered for identification under the state's air toxics identification program.

What is the California Program for Identification and Control of TACs?

This program is required by a California law which took effect in 1984 (AB 1807, Tanner, Chapter 1047, statutes of 1983, Health and Safety Code sections 39650-39674). This statute created a comprehensive program administered by the ARB to address the adverse public health impacts caused by emissions of toxic substances to the ambient air.

The program consists of a two-phase process which separates risk assessment (identification) from risk management (control). During the identification phase, a report is developed which determines whether there are potential adverse health effects from substances in consideration of the quantities of their emissions and human exposure in California. If the Board formally identifies a substance as a toxic air contaminant, it enters the risk management phase. In the risk management phase, the ARB staff determines the need for and appropriate degree of controls in consideration of cost and potential health benefits. Both the identification phase and control phase are open public processes in which the ARB staff actively seeks industry and public participation.

What are the Requirements of the Health and Safety Code Sections 39660 - 39662 for Identification of Substances as TACs?

Health and Safety Code section 39660 (f) requires that the following criteria to prioritize compounds for evaluation as possible TACs: 1) risk of harm to public health, 2) amount or potential amount of emissions, 3) manner of, and exposure to, usage of the substance in California, 4) persistence in the atmosphere, and 5) ambient concentrations in the community.

In consultation with the OEHHA staff, the ARB staff prepares a report that serves as the basis for regulatory action. Health and Safety Code section 39660 requires that, upon the request of the ARB, the OEHHA evaluates the health effects of a potential toxic air contaminant while the ARB evaluates the exposure data associated with it.

The ARB's exposure assessment is based, to the extent available, upon research and monitoring data, emissions inventory data, toxic chemical release data, and information on estimated actual exposures from data on ambient and indoor air environments [Health and Safety Code section 39660(f)].

The OEHHA's health evaluation includes an assessment of the availability and quality of data on health effects, including potency and mode of action. Where it can be established that a threshold of adverse health effects exists, the estimate must include a safe exposure level and an explanation of the uncertainties of the data. If there is no threshold of significant adverse health effects, a range of risk for exposure is determined.

The report, together with the scientific data on which the report is based, is made available to the public and is formally reviewed by the Scientific Review Panel (SRP or Panel) pursuant to Health and Safety Code section 39661. The SRP reviews scientific procedures and methods used to support the data, the data itself, and the conclusions and assessments on which the report is based. The SRP submits its findings on the report, and may reject the report if the SRP finds it to be seriously deficient. If so, the report is revised by the staff and again reviewed by the Panel. Subsequent to the SRP review, the Board conducts a public hearing to determine, based on the staff's report and the SRP findings, if a substance should be listed as a TAC. If the Board decides to list the substance as a TAC, it is added to section 93000 of the California Code of Regulations.

What is Inorganic Lead?

Lead (Pb) is a bluish gray metal that occurs naturally in various mineral forms in the earth's crust. It has been widely used for hundreds of years because it is readily shaped and molded, and is resistant to corrosion. "Organic lead" refers to lead compounds which contain carbon; "inorganic lead" refers to those substances that do not contain carbon and includes metallic lead. This report focuses on inorganic lead compounds because the most significant outdoor exposure in California is from inorganic lead particulate matter. For the purposes of this report, inorganic lead and lead are used interchangeably.

Is There a Concern for Exposure to Inorganic Lead in California?

Yes. California is in attainment (average ambient air measurements are well below the federal and state ambient air quality standards) for lead. However, new information has been reported on the health effects of lead since the adoption of the ambient air quality standards approximately 20 years ago. Lead is now considered a potential human carcinogen. However, neurodevelopmental effects in children and increases in blood pressure and related cardiovascular conditions in adults are more significant health concerns from ambient air lead exposure than cancer. Furthermore, it is now known that these effects can occur from exposures below the ambient air quality standard. Therefore, although at current average ambient levels, air lead is a minor contributor to children's exposure, ambient and near-source exposures may still present a potential public health concern. This report contains the technical information which serves as the basis for consideration of inorganic lead as a TAC under state law.

What are the Sources of Inorganic Lead Emissions?

The major sources of outdoor emissions in California include: stationary point and area source fuel combustion, aircraft fuel combustion, industrial metal melting, autobody refinishing, cement manufacturing, and incineration. Also, inorganic lead emissions may deposit and accumulate in soil for many years. These lead-contaminated particles including dust particles can be re-entrained (resuspended) by wind and agricultural activities.

How Much Inorganic Lead is Released into California's Air?

Based on information from local air pollution control districts and surveys conducted by the ARB staff, an estimated 175 to 182 tons of inorganic lead are directly emitted to California's atmosphere each year. We estimate that sources of aircraft fuel combustion emit 149 tons per year, and non-ferrous and ferrous metal melting facilities emit approximately 6 tons per year. The ARB staff estimates that re-entrained lead contributes approximately 390 tons of lead per year to California's atmosphere. Most of the lead emitted into ambient air is expected to be associated with particles smaller than 10 micrometers in size; however, resuspended dust may also have particles greater than 10 micrometers. Particles less than 10 micrometers in size are of health concern because of their ability to bypass the body's natural defense systems and their potential for long residence time in the lung. Although particles greater than 10 micrometers may not be respirable, they are also of health concern because they may be inhaled and swallowed or can deposit on food or water which could ultimately lead to ingestion.

Are Emissions of Inorganic Lead Expected to Change in the State?

At this time, the ARB staff do not have sufficient information to determine whether overall emissions in California will increase or decrease. Emissions from non-ferrous metal melting facilities have decreased (as demonstrated by near source ambient air monitoring) since the adoption of an air toxic control measure (ATCM) adopted by the Board in January 1993. Re-entrainment of lead from soil dust is expected to decrease because of the removal of lead from fuel. Emissions from cement manufacturing may increase because manufacturers may use tires which contain lead, as a new source of fuel for cement kilns.

In January 1992, remaining lead additives used in fuels were banned for use in on-road vehicles in California. Consequently, emissions of lead from this source category will be virtually eliminated. Nationally, the federal Clean Air Act prohibited the use of leaded fuel in on-road vehicles after December 31, 1995. However, both in California and nationally, leaded fuel may still be used in aircraft. In addition, off-road vehicles such as pleasure-craft and farm implements may also use leaded fuel; however, these vehicles are expected to obtain fuel from the same fuel distribution system as on-road vehicles.

What are the Ambient Outdoor Air Concentrations of Inorganic Lead?

The ARB staff's detailed analysis of the ambient outdoor concentrations of inorganic lead are based on data collected in 1990-91 from the ARB's criteria pollutant monitoring network. Mean annual concentrations ranged from a minimum of 0.02 micrograms per cubic meter to 0.12 micrograms per cubic meter. The statewide population-weighted exposure is estimated to be 0.06 micrograms per cubic meter. The ARB staff also reviewed ambient monitoring data immediately after the January 1992 full ban (January to June 1992) of lead in automobile fuel. It shows a range of mean concentrations from 0.01 to 0.08 micrograms per cubic meter. It is expected that more recent measurements of ambient concentrations of lead are lower. Further updates of ambient concentrations will be conducted after inorganic lead is identified as a toxic air contaminant by the Board.

Are There Near-Source Exposures to Inorganic Lead in California?

Yes. Measurements made by the South Coast Air Quality Management District (SCAQMD or District) of ambient air concentrations of lead near two secondary lead recycling facilities were used to assess the potential impact of emissions on the nearby populated areas in the South Coast Air Basin. In 1992, measurements taken less than two kilometers from these facilities have shown average, monthly ambient lead concentrations as much as 52-fold higher near one of the facilities than the South Coast Air Basin mean annual ambient lead concentration of 0.07 micrograms per cubic meter. This 52-fold value is the highest average monthly ambient lead concentration and was measured at a monitoring site located in a local railroad yard, approximately one mile away from a residential area, during a period of construction at the facility. This measurement downwind of the facility was more than double the state standard of 1.5 micrograms per cubic meter averaged over 30 days.

In 1992, the District adopted a rule to reduce emissions of lead from stationary sources, Rule 1420 - Emission Standards for Lead. Using a conservative modeling approach, the SCAQMD estimated that a facility which emits 0.5 pounds per day of inorganic lead has the potential to exceed the state's ambient air quality standard for lead of 1.5 micrograms per cubic meter for a 30-day period. Rule 1420 requires facilities that use or process more than two tons of lead per year, and have maximum daily lead emissions of 0.5 pounds per day or more, to install or upgrade emission controls on equipment and processes to certain specifications. The District estimated that approximately 125 facilities have emissions at this rate or greater, and it requires these facilities to conduct modeling or monitoring to ensure that the remaining emissions do not exceed the state ambient air quality standard. The rule also requires facilities to practice good housekeeping to minimize lead emissions from fugitive dust sources. As a result of SCAQMD's monitoring, these two secondary lead recycling facilities have taken steps to reduce emissions and significant reductions in ambient air concentrations have been observed. Recent data taken near the facilities have shown annual average concentrations on the order of 0.24 micrograms per cubic meter.

The ambient measurements reflect the following: emissions from the secondary lead recycling facilities including the construction activities at one of the facilities, lead contributed from other sources, and re-entrained lead from surface deposition. The SCAQMD samplers were placed as near as possible to the expected site of maximum ground level concentration. Monthly means were measured. The results do not represent maximum annual concentrations because of frequent variations in local meteorology and because samples were not collected daily.

Is There Evidence of Indoor Air Exposure to Inorganic Lead?

Yes. However, indoor concentrations of airborne lead are typically lower than outdoor concentrations. Most of the lead present in the indoor air of non-occupational environments appears to result from the infiltration of lead particles from outdoor air. However, certain activities that disturb lead-based paint, such as remodeling or paint removal, can release large amounts of lead-bearing particles into the air. Lead was a major ingredient in many types of house paint prior to the 1950s. In the early 1950s, other pigment materials gained popularity, but lead compounds were still used in some pigments and as drying agents. Lead has been banned for use in residential paint since 1978 but remains on interior and exterior surfaces of an estimated 8.6 million housing units in California. Of the 8.6 million housing units built before 1978 in California, 2.2 million homes were built before 1950 and are likely to contain lead-based paint. Lead-based paint, however, is still allowed to be used in industrial, military, and marine applications. Other potential sources of lead in indoor air are re-suspension of lead-bearing dusts, second-hand smoke, and certain hobbies that use melted lead or lead glazes.

Are There Other Routes of Exposure to Inorganic Lead?

Yes. Inorganic lead may be present in air, water, soil, foods, consumer products, dust and lead-based paint chips. While this document is especially concerned with the impact of airborne inorganic lead, at current ambient concentrations, air lead, on average, is a minor contributor to a child's overall lead exposure. People may be exposed to particulate lead emissions when the lead settles onto water, soil, vegetation, and other surfaces which are ingested or upon contact, absorbed through the skin. Lead particulate matter is the primary form of lead present in the air. Once absorbed, lead is distributed throughout the body.

The greatest source of waterborne human exposure is drinking water contaminated with lead which is leached from plumbing. Currently, the national action level for lead in drinking water is 15 parts per billion. Nationwide, public water agencies are required to evaluate households with tapwater concentrations exceeding 15 parts per billion of lead for repair. People may also be exposed to lead when plants that take up lead from the soil are consumed. The United States Environmental Protection Agency (U.S. EPA) reports that the typical soil lead "background" concentration is about 15 milligrams per kilogram or parts per million (ppm); however, soils near emissions sources may have concentrations 100-fold higher or more. In 1982, soil samples collected throughout the San Joaquin Valley had lead concentrations ranging from 3 to 99 milligrams per kilogram or ppm with a mean of 17 milligrams per kilogram or ppm. The U.S. EPA has also reported that livestock forage located 25 meters from roads with high-traffic density have shown lead concentrations ranging from 20 to 950 milligrams per kilogram or ppm. Lead solder in food containers can be another source of exposure to lead. However, only approximately one percent of canned goods currently use lead solder.

Most cases of chronic lead poisoning in children result from the ingestion of lead-based paint and contaminated soil. Lead poisoning can also occur in some ethnic cultures as the result of the use of traditional medicines containing high concentrations of lead. The greatest opportunity for lead-based paint exposure occurs when painted surfaces are refinished or remodeled. The federal Department of Housing and Urban Development initiates lead abatement in public housing where lead concentrations are above 5,000 milligrams per kilogram or ppm in the paint. In a study of about 1,000 homes in Oakland, Sacramento, and Los Angeles, approximately 25 percent of the households had lead concentrations of 5,000 milligrams per kilogram or ppm or above in the paint. Homes built prior to 1950 may contain paint with lead concentrations as high as 500,000 milligrams per kilogram or ppm (50 percent lead). In 1978, the Consumer Products Safety Commission limited the manufacture of lead-based paint.

What is the Persistence of Inorganic Lead in the Atmosphere?

Particles which contain inorganic lead are expected to have an atmospheric lifetime of up to 30 days. As mentioned previously, inorganic lead is emitted and atmospherically transported in the form of small particulate matter (less than 10 micrometers in diameter). Many factors, such as physical characteristics and meteorological conditions, affect the lifetime of lead in the atmosphere. The primary mechanisms for removal of inorganic lead particulate matter from the atmosphere are wet and dry deposition. After removal from the atmosphere and being deposited on the ground and soil, inorganic lead may be re-entrained into the atmosphere by wind and traffic.

What are the Health Effects of Inorganic Lead Exposure?

The health effects of inorganic lead have been reviewed and evaluated to determine whether inorganic lead may cause or contribute to an increase in mortality or serious illness. Based on current knowledge, adverse health effects that may occur at relatively low blood lead concentrations include: (1) neurodevelopmental effects in children, (2) increased blood pressure and related cardiovascular conditions in adults, and possibly (3) cancer. Of these three outcomes, the neurodevelopmental effects may be of greatest public health significance since a large number of children could be affected, no threshold has been clearly identified, and the effects may be irreversible.

Neurodevelopmental Effects of Lead Exposure in Children

At very high blood lead concentrations (80 micrograms per deciliter and above in children), lead causes encephalopathy (brain damage) and an associated high risk of death. Many children with blood lead levels in this range, with or without evidence of encephalopathy, experience permanent neurological damage such as severe mental retardation and recurrent convulsions.

At low blood lead concentrations, several carefully conducted prospective human epidemiological studies have shown an association between general measures of intelligence and both pre- or post-natal blood lead concentrations. Studies of effects at earlier ages appear stronger and more consistent than effects from pre-natal exposures. Based on these studies, a blood lead level of 10 micrograms per deciliter has been identified by the U.S. Centers for Disease Control (CDC) as the level of concern for children.

Based on these findings, the OEHHA staff concurs with the U.S. EPA, the CDC, and the National Academy of Sciences that 10 micrograms per deciliter should be regarded as the level of concern for children. A no observed adverse effect level (NOAEL) has not yet been clearly identified, and an analysis, specifically focusing on the determination of a threshold, was unable to detect one.

Increase in Blood Pressure and Related Cardiovascular Conditions in Adults

Lead in the environment, including the occupation setting, has also been correlated with increased blood pressure and related cardiovascular effects in adults. Several large population-based studies have examined the relationship between blood lead and either systolic or diastolic blood pressure. A relationship between systolic and diastolic blood pressure and blood lead has been reported over a wide range of blood lead levels as low as 4 micrograms per deciliter for middle-aged Caucasian men, with some studies reporting evidence of effects in women, other races, and other age groups.

Cancer

Lead can cause gene mutations and cell transformation in mammalian cells in culture. Lead also interferes with DNA synthesis in mammalian cell in culture. Many studies have shown that feeding lead compounds to rodents induces kidney tumors. Available epidemiologic studies of people occupationally exposed to lead give some indication that occupational exposure to lead may cause cancer. However, in these studies, lead was only one of several known or putative carcinogens present in the occupation environment.

The International Agency for Research on Cancer (IARC) has placed lead in Class 2B, possibly carcinogenic to humans, based on sufficient evidence of carcinogenicity from oral exposure studies in animals and inadequate evidence of carcinogenicity in humans. Likewise, the U.S. EPA has placed lead in Group B2, probable human carcinogen, based on sufficient evidence of carcinogenicity from oral exposure studies in animals and inadequate or no data from epidemiological studies.

What is the Risk Assessment for Exposure to Inorganic Lead?

The OEHHA has conducted a risk assessment for the three adverse health effects that may occur at relatively low blood lead concentrations: neurodevelopmental effects in children, increased blood pressure and related effects in adults, and possibly cancer. Since our understanding of lead's toxicity is based on blood lead levels, OEHHA also examined the relationship between lead in air and lead in blood.

Evaluation of Blood Lead/Air Lead Slope

Existing studies indicate a consistent association between ambient concentrations of lead in the air and subsequently measured blood lead levels in children and adults. The OEHHA used these studies as the basis for an "aggregate" model which quantitatively relates exposures from ambient air lead concentrations to blood lead levels, both directly through inhalation and indirectly through other media impacted by airborne lead, such as soil and household dust. With this aggregate model, risks could be estimated that relate different levels of ambient air lead to potential adverse neurodevelopmental outcomes. Current evidence suggests that the blood lead to air lead relationship for adults is approximately 1.8 micrograms per deciliter per 1 microgram per cubic meter, while the relationship for children is approximately 4.2 micrograms per deciliter per 1 microgram per cubic meter with a reasonable range of 3.3 to 5.2 micrograms per deciliter per 1 microgram per cubic meter. These slopes are assumed to be linear within the range of blood and air concentrations currently experienced in California.

Impact of Air Lead on Distribution of Blood Lead Levels

The health impacts of airborne lead were evaluated in two ways. First, OEHHA used the aggregate model discussed above to relate changes in air lead to changes in blood lead. Second, OEHHA used a model developed by the U.S. EPA called the Integrated Exposure Uptake Biokinetic (IEUBK) model. The IEUBK can incorporate both direct and indirect pathways of exposure. Model outputs from the IEUBK vary with initial air concentration and baseline levels of dust and soil lead.

Data from the third National Health and Nutrition Examination Survey (NHANES III), representative of the U.S. population, were used to estimate the current blood lead distributions for residents of California. The effects of changes in air lead on the distribution of blood lead for the subgroup of children with the highest mean blood lead levels, one and two year old children, were determined. Using both the aggregate and IEUBK models, OEHHA estimates that exposure to the 1990-91 ambient airborne lead concentration of 0.06 micrograms per cubic meter may elevate between 0.6 percent and 2.3 percent of the population of one- and two-year-old children above the 10 micrograms per deciliter level of concern. With an estimated 1.2 million one and two year old children in California, this represents between 7,200 and 27,600 children that are predicted to be above the 10 micrograms per deciliter blood lead level of concern. In addition, based on current estimates on the distribution of blood lead levels, 131,000 one- and two-year-old children who are estimated to already be at or above 10 micrograms per deciliter (even at zero air lead) could be additionally impacted. At a hypothetical elevated exposure, an air lead concentration of 0.20 micrograms per cubic meter could cause an additional 3 percent of the children exposed on average to this air lead level, to exceed the level of concern in a localized area.

Neurodevelopmental Effects Risk Assessment

For neurodevelopmental effects of lead, the results of the prospective cohort studies indicate a potential mean decrease of 1.39 IQ points per microgram per cubic meter of air lead. Applying this mean change to the cohort of 4.73 million children in California below the age of 7 suggests that the 1990-91 ambient lead concentration of 0.06 micrograms per cubic meter is associated with a potential decrease of 392,000 IQ points or, a mean decrease of 0.08 IQ points per child. A small difference in a mean score between two groups can result in large differences in the proportion of the population at extreme values, since the entire distribution is shifting. The percentage of children with IQ scores equal to or less than 80 is predicted to increase from 10.56 percent, at a zero air lead concentration, to 10.66 percent at an air lead concentration of 0.06 micrograms per cubic meter. This represents a relative increase in the number of such children of approximately one percent (i.e., (10.66-10.56)/10.56 x 100). Based on a cohort of 4.73 million children in California below age 7, the 0.06 micrograms per cubic meter average air lead concentration relates to approximately 4,700 additional children that would be predicted to have IQ levels below 80, relative to a zero air lead level. Each subsequent year, the model estimates an additional 780 children to have IQ levels below 80. At a hypothetical elevated concentration of 0.20 micrograms per cubic meter, above the current ambient average, would theoretically result in an average decrease of 0.28 IQ points in exposed children. A 0.28-point shift in mean IQ would correspond to a relative increase of approximately three percent in the number of children with scores below 80 (i.e., (10.97-10.66)/10.66 x 100).

Increase in Blood Pressure and Related Cardiovascular Effects Risk Assessment

Exposure to air lead has been associated with an increase in blood pressure and related cardiovascular effects, including hypertension. The document quantifies the risks for blood pressure changes in adults associated with changes in ambient air lead concentrations. Our model estimates increases in the diastolic blood pressure and how the increases may result in hypertension (increase in the diastolic blood pressure greater than or equal to 90 millimeters of mercury), heart attacks, or mortality. These effects are based on epidemiologic studies from which it is generally difficult to prove causality. Therefore, controversy remains about the precise magnitude of the effect of blood lead on cardiovascular disease.

The estimates from our model indicate that the 1990-91 average ambient air lead concentration of 0.06 micrograms per cubic meter may account for 26,000 cases of hypertension (95 percent confidence interval is 6,100 to 60,800) among 3.96 million California adults aged 40 to 59. In addition, the 1990-91 ambient air lead levels may result in 72 additional fatal and non-fatal heart attacks and coronary heart disease deaths (95 percent confidence interval is 12 to 164) and 74 additional deaths (95 percent confidence interval is 9 to 218) per year among 7.92 million adults in California aged 40 to 59 (See Table 1 of the attached SRP Findings). Although some of the health outcomes are derived from nonlinear models, linear approximations fit the data reasonably well over ranges seen in California, and can be used to estimate the impacts of changes in air lead concentrations or diastolic blood pressure.

Cancer Risk Assessment

The OEHHA staff performed a quantitative estimate of unit cancer risk from inorganic lead. This estimate of unit cancer risk was based on data from oral exposure studies in rodents because there are inadequate data in humans. By extrapolation of rodent data (from animals to humans and from ingestion to inhalation), the OEHHA determined a range of unit cancer risk values for humans and also a best value of unit cancer risk. From the available studies on inorganic lead, the range of unit cancer risk is 1.2×10^{-5} to 6.5×10^{-5} per microgram per cubic meter for a lifetime exposure to 1 microgram per cubic meter of lead based on the no identifiable threshold assumption for lead-induced carcinogenicity and using the linearized multistage model. The best value of 1.2×10^{-5} per microgram per cubic meter, based upon the latest and best animal study data set, can be used for quantitative cancer risk assessment.

Using the OEHHA staff's range of risk values and the 1990-1991 statewide mean annual population-weighted exposure of 0.06 micrograms per cubic meter, exposure to this level of inorganic lead could result in 0.7 to 4 potential cancer cases per 1 million people exposed by direct inhalation for a 70-year lifetime. Based on a population of 34 million, it is estimated that the cancer burden for California residents may be approximately 24 to 136 potential excess cancer cases statewide (assuming a lifetime of exposure) from direct inhalation only. Using the OEHHA staff's best value of 1.2×10^{-5} per microgram per cubic meter, exposure to ambient inorganic lead may result in 0.7 potential cancer cases per 1 million, with a cancer burden of 24 among the 34 million residents of California. This estimate represents the upper range of plausible excess cancer risk and the potential number may be significantly lower and possibly zero if a threshold mechanism exists for lead-induced carcinogenicity. A multipathway risk assessment which includes risk impacts from dust and soil contamination would increase the risk estimate. Table 2 of the attached SRP Findings shows a comparison of the inorganic lead cancer potency with other compounds the Board has identified as TACs.

What are the Uncertainties Associated with the Risk Assessments?

Unlike most toxicological risk assessments and previous assessment of TACs, most of our conclusions are based on human studies except those for cancer. The uncertainties in the risk assessments for adverse neurodevelopmental effects and increased blood pressure are considered to be much less than those for the cancer endpoint. Four major uncertainties, usually encountered in cancer risk assessments, are those due to (1) animal-to-human extrapolation, (2) high-to-low dose extrapolation, (3) accounting for sensitive members in the human population, and (4) small numbers of subjects. Regarding animal-to-human extrapolation, the cancer effect results from oral exposure studies in animals are extrapolated to derive an inhalation unit risk for humans.

For the noncancer endpoints from lead exposure, the data used were obtained in humans so that uncertainty introduced by extrapolation is not an issue. The second concern, the degree of uncertainty introduced by extrapolation from high to low doses, is small for the noncancer endpoints and several orders of magnitude for the cancer effects. Only limited extrapolation is necessary for the noncancer effects, since most results have been obtained at blood lead levels within a factor of two to five of the current estimated mean blood lead levels in California.

The third source of uncertainty, differential sensitivity in the population, is relativity small for adverse neurodevelopmental effects and increased blood pressure, since sensitive individuals were considered within the studies evaluated. The fourth source of uncertainty, arising from the small numbers of subjects evaluated in the animal cancer studies, is relatively insignificant for the noncancer health effects. For the noncancer health effects of lead, there are multiple studies on neurodevelopmental effects and more than 10,000 adults in the blood pressure studies. Consequently, the uncertainty in the noncancer risk assessment for lead is small relative to that usually encountered in risk assessments for toxic chemicals including the lead cancer risk assessment for this document.

The risk and potential health impact calculations should not be interpreted as precise measurements or probabilities of mortality or morbidity associated with exposure to inorganic lead. Although based upon the best available scientific data, the calculations are derived from models which contain many assumptions and uncertainties. Uncertainty is inherent in the application of relatively small changes in the blood lead levels and associated physiological or neurological effects to large populations assumed to be exposed on average to the California's average ambient air lead level. The risk estimates are useful in providing a perspective and appreciation for the potential magnitude and severity of individual health threats and populations impacts.

Is There a Threshold Level for Inorganic Lead?

Based on information available, there is no clearly established threshold level for lead-induced toxicity. Therefore, should inorganic lead be identified as a TAC, it is recommended that a qualifying statement be included which indicates there currently is no evidence of an identified threshold for neurotoxicity, increased blood pressure and related cardiovascular effects, or possible carcinogenicity.

What has been Done to Reduce Exposure to Inorganic Lead?

The state has taken a number of actions to reduce exposure to lead in California. In November of 1970, California adopted an ambient air quality standard for lead based on a 30-day running average of 1.5 micrograms per cubic meter. The state standard is a monthly average as contrasted to the 1978 federal standard of 1.5 micrograms per cubic meter averaged over a calendar quarter. The 1978 federal standard of 1.5 micrograms per cubic meter is based on preventing children from exceeding a blood lead level of 30 micrograms per deciliter of blood.

In the early 1970's, this standard was exceeded in many areas of the state. However, emissions of lead into ambient air from mobile sources have decreased significantly since 1975 because of regulations phasing out the use of lead in fuel with the introduction of catalyst-equipped vehicles. Between 1978 and 1987, the consumption of leaded-gas decreased by 90 percent and total lead emissions were reduced by 94 percent. As a result of these regulatory efforts, the state is now in attainment of the state and federal ambient lead standards at all of our ambient monitoring locations. In January 1992, the ARB regulation prohibiting the sale of leaded fuel for on-road motor vehicle use went into effect. These regulations are estimated to have virtually eliminated statewide lead emissions from on-road motor vehicles.

In January 1993, the Board also adopted an air toxic control measure that reduces emissions of toxic metals from non-ferrous metal melting facilities such as smelters, foundries, die casters, and galvanizing operations. As a side benefit, emissions of lead from non-ferrous metal melting operations is expected to have been reduced by 45 percent. The control measure was written specifically to address emissions of arsenic, cadmium, and nickel which all have previously been identified as TACs in California. This control measure is expected to have reduced emissions of lead from non-ferrous metal melting facilities in the South Coast Air Basin and should reduce ambient air lead levels in the immediate vicinity of the facilities implementing the required controls. The emission reductions have been achieved by collecting emissions from furnace and casting operations and ducting them to best available equipment for control of particulate emissions, and by requiring control of fugitive emissions.

Further, as discussed on page 5, in 1992 the SCAQMD adopted Rule 1420 to require that facilities do not release emissions beyond the property line of the facility which cause ambient concentrations of lead to exceed the state ambient lead standard. According to the SCAQMD staff, this rule is expected to reduce lead emissions by nearly 80 percent, which corresponds to 10.5 tons.

In addition to the air toxic control measure and Rule 1420, several other programs may have contributed to emission reductions of inorganic lead. As part of the Air Toxics "Hot Spots" Information and Assessment Act (AB 2588), the ARB staff is aware that a number of facilities have taken voluntary steps to reduce emissions of air toxics. This may also be the case for facilities subject to Proposition 65 (California's Safe Drinking Water and Toxic Enforcement Act of 1986), and Superfund Amendments and Reauthorization Act of 1986 (SARA) Title III requirements (Emergency Planning and Community Right-to-Know Act). However, comprehensive information on voluntary emission reductions as a result of these other programs is not available.

Also, the ARB and the OEHHA staff have participated in the Environmental and Consumers Sources Workgroup for the development of the Strategic Plan to Eliminate Lead Poisoning in California which is being lead by the California Department of Health Services. The purpose of the workgroup was to develop goals, problem statements, and strategies for the elimination of lead poisoning in waste disposal, air, water, and consumer products. The plan is nearing completion of public comment and is expected to be implemented in the future.

How Does This Information Affect Proposition 65?

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) differs and is separate from the toxic air contaminant program. Proposition 65 requires a person to warn if he/she cannot show that exposures caused in the course of doing business, (1) by carcinogens on the Proposition 65 list pose no significant cancer risk or (2) by male and female reproductive toxicants or developmental toxicants on the Proposition 65 list have no observable effect assuming exposure at one thousand times the level in question.

A specific reference exposure level for reproductive effects has not been developed in the toxic air contaminant program. The Proposition 65 safe harbor level for the reproductive effects of lead is not affected by this review.

The range of cancer unit risk developed for the toxic air contaminant program is for inhalation of inorganic lead (Title 22, California Code of Regulations, Section 12705). Under

Proposition 65 no significant risk levels (for cancer) have been adopted for lead acetate and lead subacetate. These values, which currently apply to both inhalation and ingestion, will be reconsidered and modified as appropriate should inorganic lead, under this program, be identified as a toxic air contaminant.

How May Risk Managers Use This Information?

The aggregate model presented in the document is a useful tool to determine the potential impact of an airborne lead concentration on the population percentage or number of children that may exceed the CDC guidelines of 10 micrograms per deciliter. However, due to the multiple sources of lead exposure and the inter-relationship of the various media, risk managers may need to examine all sources of lead to determine the most effective manner to reduce childhood blood lead levels for a given community. The IEUBK model, which can incorporate local inputs from field measurements, may provide useful information when considering various mitigation strategies. Further risk management guidance in this area is recommended to be developed by ARB staff, with the assistance of OEHHA staff. This guidance would contain any updated statewide population-weighted concentrations.

Has the Staff Conducted an Assessment of the Economic Impacts?

Based on the evidence available, the identification of inorganic lead as a TAC will not require any private person or business, including any small business, to incur any cost in reasonable compliance with the proposed action. If, and when, the need and appropriate degree of control for inorganic lead are considered by the ARB during the risk management process, all costs of compliance will be described and considered. The reasons that the identification of inorganic lead as a TAC is not anticipated to have any adverse economic impacts on businesses are discussed below.

The recommended OEHHA cancer risk number for inorganic lead is approximately seven times lower than the cancer risk number that has been used historically by the local air pollution control districts and the California Environmental Protection Agency for cancer risk assessments. Therefore, the ARB does not anticipate any adverse economic impacts on businesses. For noncancer, the ARB and the OEHHA staff propose to develop, in a full open public process, further risk management guidance in this area.

Why Does the Staff Recommend Inorganic Lead be Identified as a TAC?

The staff of the ARB and the OEHHA have reviewed the available scientific evidence on the presence of inorganic lead in the atmosphere of California and its potential adverse effect on public health. The staff has found that lead is emitted from a variety of sources, is found throughout California in ambient air, is persistent in the environment, and may be re-entrained in the atmosphere. Inorganic lead has been associated with many different health effects which include neurodevelopmental effects in children, increases in blood pressure and related cardiovascular conditions in adults, and possibly cancer. Both the U.S. EPA and IARC have concluded that, based on oral exposure studies in laboratory animals, inorganic lead is a potential carcinogen. Based on neurotoxicity, increases in blood pressure and related cardiovascular effects, and potential human carcinogenicity, the OEHHA staff has found that, inorganic lead has the potential to be an air pollutant that may cause or contribute to an increase in mortality or an increase in serious illness, or that may pose a present or potential hazard to human health. Therefore, the OEHHA staff and the ARB staff conclude that inorganic lead meets the definition of a TAC supported by the findings of neurotoxicity, increases in blood pressure and related cardiovascular effects (increased risk for fatal and nonfatal myocardial infarction, death from coronary heart disease), carcinogenicity, and direct human exposure.

Commencing in the late 1970's, there has been substantial reduction in exposure to lead from environmental sources. On a nationwide basis, from 1976 to 1990, the amount of lead used in gasoline decreased 99.8 percent. The use of lead soldered food and drink cans has declined substantially from nearly 50 percent in 1980 to approximately 1 percent today. The manufacture of lead-based paint was limited by the Consumer Products Safety Commission in 1978. In California, the annual average ambient air lead levels have declined approximately 30-fold from the mid-1970's. Similarly, cross section national surveys conducted by the CDC indicate a dramatic decline in blood lead levels from NHANES II (1976 to 1980) to NHANES III (1988 to 1991). NHANES II (1976 to 1980) estimated 88.2 percent of 1 to 5 year old children in the United States exhibited blood lead levels greater than or equal to 10 micrograms per deciliter. A decrease in mean blood lead levels of greater than 70 percent was observed for all subgroups stratified by age, race/ethnicity, gender, urban status and income levels, in comparing NHANES III to NHANES II.

Despite the dramatic reduction in environmental lead levels, and the concomitant decrease in blood lead levels in the population as a whole, there remains concern for populations who may experience disproportionately higher lead exposures. For example, blood lead level surveys conducted by the California Department of Health Services indicate there are communities within urban areas of California with a disproportionate percentage of children with blood lead levels greater than 10 micrograms per deciliter. Similarly, NHANES III indicates that the percentage of children aged 1 to 5 with blood lead levels greater than, or equal to, 10 micrograms per deciliter is disproportionately higher, on a nationwide basis, for non-Hispanic African-American children. The major remaining sources of environmental lead that may pose a public health threat appear to be localized sources of lead, including, but not limited to, continued deterioration of lead-based painted surfaces in older buildings, lead that has already accumulated in dust and soil, and near sources of air lead emissions.

What are the Findings of the Scientific Review Panel?

Findings of the Scientific Review Panel on
THE REPORT ON INORGANIC LEAD
as Adopted at the Panel's October 31, 1996 Meeting

Pursuant to Health ant Safety Code section 39661, the Scientific Review Panel (SRP/Panel) has reviewed the report Proposed Identification of Inorganic Lead as a Toxic Air Contaminant by the staffs of the California Air Resources Board (ARB or Board) and the Office of Environmental Health Hazard Assessment (OEHHA) on the public exposure to, and health effects of, inorganic lead. The Panel members also reviewed the public comments received on this report. Based on this review, the SRP makes the following findings pursuant to Health and Safety Code section 39661:

1. Lead is known to cause significant noncancer health effects. The two noncancer health effects of most concern at low blood pressure and related cardiovascular effects in adults. The neurodevelopmental and cardiovascular effects likely have the most public health significance.

2. There is relatively little uncertainty in the risk assessments for the noncancer endpoints for lead, including neurodevelopmental and blood pressure effects compared to the cancer endpoint. Four major uncertainties associated with most risk assessments are animal to human extrapolation, high to low dose extrapolation, full consideration of sensitive members of the human population, and studies with small numbers of subjects. The uncertainty for the noncancer risk assessment for lead is small because it includes human and low dosage data, full consideration of sensitive members of the human population, and studies that contain numerous subjects.

3. Scientific studies have indicated that, at low to moderate blood lead levels, neurodevelopmental effects include: decreased intelligence, short term memory loss,

reading and spelling underachievement, impairment of visual motor functioning, poor perception integration, disruptive classroom behavior, and impaired reaction time.

4. The data on the effects of lead on measures of intelligence are particularly compelling. Evidence from three prospective cohort studies show a relationship between blood lead levels and intelligence in children up to 10 years of age. The effects on intelligence appear to occur above and possibly below the 10 micrograms per deciliter "level of concern" identified by the Centers for Disease Control (CDC) and the National Academy of Sciences. A threshold for neurodevelopmental effects from lead exposure has not been identified. Based on scientific evidence for neurodevelopmental effects, and increase of 1 microgram per cubic meter of lead in ambient air inhaled would, on average, lead to a decrease of approximately 1.32 intelligence quotient (IQ) points for children below the age of 10. Based on an evaluation of peer-reviewed evidence, it is estimated that there would be a mean decrease of 0.08 IQ points for children below the age of 10 exposed to the mean annual 1990-91 population-weighted exposure of 0.06 micrograms per cubic meter of airborne lead. While this effect may seem insignificant at the individual level, it would result in a downward shift in the distribution in IQ points for children in an exposed community. For example, at the ambient average air lead concentration of 0.06 micrograms per cubic meter, the models predict that 4,700 additional children in California have IQ levels below 80 relative to a zero air lead level.

5. Based on current scientific evidence and using blood lead data provided by the recent National Health and Nutrition Examination Survey (NHANES III), the percent of children that would move above the 10 micrograms per deciliter blood level of concern established by the CDC and accepted by OEHHA, can be calculated. The evidence suggests that at the mean annual 1990-91 statewide population-weighted lead level, an additional 0.6 to 2.3 percent of children between the ages of 1 and 2 could move above 10 micrograms per deciliter. The amounts to between 7,200 and 27,600 children in California. At an air lead concentration of 0.25 micrograms per cubic meter, the models indicate that an additional

5 to 13 percent of the children in this age group would move above 10 micrograms per deciliter.

6. Increases in both systolic and diastolic blood pressure and cardiovascular effects have been correlated with lead exposure. There are many large population-based studies that examine the relationship between blood lead levels and hypertension (diastolic blood pressure greater that or equal to 90 millimeters of mercury). In addition, scientific evidence indicates a consistent association between increases in blood pressure and increases in more serious cardiovascular outcomes.

7. Based on this evidence, exposure to the mean annual 1990-91 statewide population-weighted airborne lead exposure of 0.06 micrograms per cubic meter is estimated to lead to 26,000 (with a 95 percent confidence interval of 6,100 to 60,800) additional cases of hypertension (diastolic blood pressure greater than or equal to 90 millimeters of mercury) among the 7.92 million adults in California between the ages of 40 and 59. In addition, the exposure to 0.06 micrograms per cubic meter of air lead is estimated to result in 72 (with 95 percent confidence interval of 9 to 218) deaths from all cardiovascular related disease per year among the 8 million adults between the ages of 40 and 59. These values equate to a unit risk for mortality from cardiovascular disease of 4.6 x 10^-4 per microgram per cubic meter (Table 1).

8. The risk assessment for potential near source exposure to inorganic lead at the annual average ambient concentration of 0.24 micrograms per cubic meter could result in a 4-fold increase in risk for neurodevelopmental effects, increased blood pressure and related cardiovascular effects, and cancer.

9. The current federal ambient air quality standard for lead developed bu the United States Environmental Protection Agency (U.S. EPA) is 1.5 micrograms per cubic meter. This standard was based on preventing blood lead levels in 99.5 percent of children from

exceeding 30 micrograms per deciliter, a level of concern that dates from 1978. The CDC has established a level of concern for children at blood lead levels of 10 micrograms per deciliter. At an air lead level of 1.5 micrograms per cubic meter, approximately one-half of California children would be expected to exceed the CDC guideline of 10 micrograms per deciliter. With current air lead levels (0.06 micrograms per cubic meter), the percentage of children exceeding the CDC guideline of 10 micrograms per deciliter is anticipated to be 11.5 percent, 0.6 percent more children than it there were not lead in the air.

10. Lead compounds (which include organic and inorganic lead compounds) are listed as federal hazardous air pollutants (HAPs) and, therefore, were identified as toxic air contaminants (TACs) by the Board on April 8, 1993. However, the federal HAPs list does not include elemental lead in the definition of lead compounds. For this process, elemental lead is included in the ARB/OEHHA definition of inorganic lead and is, therefore, being considered for identification under the state's air toxics program.

11. The major source of inorganic lead in ambient outdoor air are estimated to emit approximately 180 tons per year. Aircraft fuel combustion is the primary source of emissions at 149 tons per year. Other sources include autobody refinishing, battery manufacturing facilities, cement manufacturing, cogeneration, sawmills, paperboard mills, foundries and steel mills, stationary source fuel combustion, incineration, paint and coatings manufactureres, sand and gravel facilities, and secondary lead recycling facilities. Inorganic lead previously emitted from such sources may be re-entrained as windblown dust; it is expected to contribute 390 tons per year into the atmosphere. Ambient levels of inorganic lead can be much higher near sources which emit lead such as those listed above.

12. Based on air monitoring data collected by the ARB's criteria pollutant monitoring network, the 1990-91 statewide population-weighted exposure is estimated to be 0.06 micrograms per cubic meter. Current *statewide* population-weighted exposure is expected to be lower due to the ban on the use of leaded fuel for on-road vehicles in California effected January 1992, the

implementation of a South Coast Air Quality Management District emission standard on lead (Rule 1420), and an air toxic control measure limiting lead emissions from stationary sources. The 1992-93 *near-source* annual average ambient concentration is 0.24 micrograms per cubic meter taken one third of a mile away from a specific secondary lead recycling facility.

13. Lead associated with particles may remain suspended in the atmosphere for up to 30 days. These particles are removed by wet and dry deposition.

14. Indoor concentrations are generally lower than outdoor concentrations; indoor/outdoor ratios range from 0.3:1 to 1:1.

15. Inhalation is not the only route of exposure to lead. Airborne lead that deposits on soil, water, and food can be ingested.

16. Most cases of lead poisoning in children are caused by ingestion of lead-based paint. Lead poisoning is also caused by the use of lead-containing traditional medicines from different cultures.

17. Scientific evidence suggests that a 1 microgram per cubic meter increase in atmospheric lead corresponds to 4.2 micrograms per deciliter (with a 95 percent confidence interval of 3.3 - 5.2 micrograms per deciliter) increase of blood lead over time for children and a 2 microgram per deciliter increase of blood lead for adults. The estimates have been developed using both an aggregate model and the U.S. EPA’s Integrated Exposure Uptake Biokinetic Model (IEUBK) which incorporate the impacts of air lead emissions through all potential pathways.

18. California ambient air monitoring data from the mid 1970's to 1991 show a substantial decrease in ambient lead concentrations. This is primarily due to leaded fuel regulations that have eliminated the use of lead in automobile fuels and the introduction of catalyst equipped vehicles.

19. The International Agency for Research on Cancer (IARC) has listed lead and Inorganic lead compounds in class 2B (1980), possibly carcinogenic to humans, based on sufficient animal carcinogenicity and inadequate human carcinogenicity data. The United States Environmental Protection Agency (U.S. EPA) has placed lead compounds in category B2(1986), probable human carcinogen, on the basis of sufficient evidence of carcinogencitiy in animals, but inadequate or not data form human epidemiological studies.

20. Scientific studies show that lead can cause gene mutation and cell transformation in culture, and can interfere with DNA synthesis. Rodents that have ingested high doses of lead show increased occurrences of kidney tumors.

21. Based on a health protective interpretation of the available scientific information, the upper-bound of the lifetime excess unit cancer risk resulting from inorganic lead exposure ranges from 1.2×10^{-5} to 6.5×10^{-5} per microgram per cubic meter. This estimate of unit cancer risk was based on rodent data because there are inadequate data in humans. The best value for unit cancer risk is 1.2×10^{-5} per microgram per cubic meter, and is based on the largest data set available for quantitative assessment.

22. Based on the best value for potential unit cancer risk of 1.2×10^{-5} per microgram per cubic meter and the mean annual 1990-91 statewide population-weighted average of 0.06 micrograms per cubic meter, there could be 0.7 potential cancer cases per million people over a 70-year lifetime. Based on a population of 34 million California residents, the cancer burden is estimated to be 24 potential cancer cases.

23. Table 2 , attached to these Findings, compares the best value of upper-bound unit cancer risk for inorganic lead with those of other compounds reviewed by the SRP. These 95 percent upper-bound lifetime risk estimates are health-protective estimates; the actual risk may be much lower.

24. Based on available information, there is no evidence for a threshold for neurotoxicity, increased blood pressure and related cardiovascular effects, or cancer.

25. Based on available scientific evidence, we conclude that inorganic lead should be identified as a toxic air contaminant.

After careful review of the September 1996 draft SRP version of the ARB report, "Inorganic Lead as a Toxic Air Contaminant," we find this report with the changes specified in our October 31, 1996 meeting as representing a complete and balanced assessment of our current scientific understanding.

For these reasons, we agree with the science presented in Part A by ARB and Part B by OEHHA in the report on inorganic lead and the ARB staff recommendation to its Board that inorganic lead be listed by the ARB as a toxic air contaminant.

I certify that the above is true and correct copy of the findings adopted by the Scientific Review Panel on October 31, 1996.

//s//
James N. Pitts Jr., Ph.D.
Chairman, Scientific Review Panel

TABLE 1

NONCANCER POTENCIES APPROVED BY THE SCIENTIFIC REVIEW PANEL 1996

Compound	Unit Risk ($\mu g/m^3)^{-1}$	Endpoint
Inorganic Lead	4.6×10^{-4}*	Cardiovascular Mortality

$\mu g/m^3$: microgram per cubic meter

* The noncancer risk is based on the predicted number of cardiovascular deaths for adults age 40 to 59. The estimate indicates an expected 74 deaths per year per 7.92 million California adults exposed to the 0.06 $\mu g/m^3$ airborne lead concentration. Therefore, the risk per $\mu g/m^3$ would be (74/7.92 million) x (1/0.06) = 1.56×10^{-4}. Using the upper 95 percent confidence estimate of 218 annual deaths for the 7.92 million California adults 40 to 59 generates a unit risk of 4.6×10^{-4}. These 95 percent upper-bound lifetime risk estimates are health-protective estimates; the actual risk may be much lower. (See Findings No.7)

TABLE 2

CANCER POTENCIES APPROVED BY THE SCIENTIFIC REVIEW PANEL FROM 1984 TO 1996
(in order of cancer potency)

Compound	Unit Risk ($\mu g/m^3)^{-1}$	Unit Risk (ppbv)
Dioxins	3.8×10^{1}	Particulate Matter
Chromium	1.5×10^{-1}	Particulate Matter
Cadmium	4.2×10^{-3}	Particulate Matter
Inorganic Arsenic	3.3×10^{-3}	Particulate Matter
Benzo[a]pyrene	1.1×10^{-3}	Particulate Matter
Nickel	2.6×10^{-4}	Particulate Matter
1,3-Butadiene	1.7×10^{-4}	3.7×10^{-4}
Ethylene Oxide	8.8×10^{-5}	1.6×10^{-4}
Vinyl Chloride	7.8×10^{-5}	2.0×10^{-4}
Ethylene Dibromide	7.1×10^{-5}	5.5×10^{-4}
Carbon Tetrachloride	4.2×10^{-5}	2.6×10^{-4}
Benzene	2.9×10^{-5}	9.3×10^{-5}
Ethylene Dichloride	2.2×10^{-5}	8.9×10^{-5}
***Inorganic Lead**	**1.2×10^{-5}**	**Particulate Matter**
Perchloroethylene	5.9×10^{-6}	4.0×10^{-5}
Formaldehyde	6.0×10^{-6}	7.0×10^{-6}
Chloroform	5.3×10^{-6}	2.6×10^{-5}
Acetaldehyde	2.7×10^{-6}	4.8×10^{-6}
Trichloroethylene	2.0×10^{-6}	1.1×10^{-5}

Compound	Unit Risk ($\mu g/m^3)^{-1}$	Unit Risk (ppbv)
Methylene Chloride	1.0×10^{-6}	3.5×10^{-6}
Asbestos	1.9×10^{-4} (per 100 fiber/m^3)	---

$\mu g/m^3$: microgram per cubic meter
ppbv: part per billion volume
*   Noncancer deaths from exposure to Inorganic Lead are more significant than cancer effects (See Table 1).

PROPOSED REGULATION ORDER

Amend Titles 17 and 26, California Code of Regulations, Section 93000 to read as follows:

93000. Substances Identified as Toxic Air Contaminants.

Each substance identified in this section has been determined by the State Board to be a toxic air contaminant as defined in Health and Safety Code Section 39655. If the State Board has found there to be a threshold exposure level below which no significant adverse health effects are anticipated from exposure to the identified substance, that level is specified as the threshold determination. If the Board has found there to be no threshold exposure level below which no significant adverse health effects are anticipated from exposure to the identified substance, a determination of "no threshold" is specified. If the Board has found that there is not sufficient available scientific evidence to support the identification of a threshold exposure level, the "Threshold" column specifies "None identified."

Substance	Threshold Determination
Benzene (C6H6)	None Identified
Ethylene Dibromide (BrCH2CH2Br)	None Identified
Ethylene Dichloride (ClCH2CH2Cl; 1,2-dichloroethane)	None Identified
Hexavalent Chromium [Cr(VI)]	None Identified
Asbestos [asbestiform varieties of serpentine (chrysotile) riebeckite (crocidolite) cummingtonite-grunerite (amosite), tremolite, actinolite, and anthophyllite]	None Identified
Dibenzo-p-dioxins and Dibenzofurans chlorinated in the 2,3,7 and 8 positions and containing 4, 5, 6, or 7 chlorine atoms	None Identified
Cadmium (metallic cadmium and cadmium compounds)	None Identified
Carbon Tetrachloride (CCl4; tetrachloromethane)	None Identified
Ethylene Oxide (1,2-epoxyethane)	None Identified
Methylene Chloride (CH2Cl2; Dichloromethane)	None Identified

Substance	Threshold Determination
Trichloroethylene	None Identified
Chloroform (CHCl3)	None Identified
Vinyl Chloride (C2H3Cl; Chloroethylene)	None Identified
Inorganic Arsenic	None Identified
Nickel	None Identified
Perchloroethylene (C2Cl4; Tetrachloroethylene)	None Identified
Formaldehyde (HCHO)	None Identified
1,3-Butadiene (C4H6)	None Identified
Inorganic Lead	None Identified

NOTE: Authority cited: Sections 39600, 39601, and 39662, Health and Safety Code.
Reference: Sections 39650, 39660, 39661, and 39662, Health and Safety Code.

TABLE 1

CANCER POTENCIES APPROVED BY THE SCIENTIFIC REVIEW PANEL FROM 1984 TO 1994
(in order of cancer potency)

Compound	Unit Risk ($\mu g/m^3)^{-1}$	Unit Risk (ppbv)
Dioxins	3.8×10^{1}	Particulate Matter
Chromium VI	1.5×10^{-1}	Particulate Matter
Cadmium	4.2×10^{-3}	Particulate Matter
Inorganic Arsenic	3.3×10^{-3}	Particulate Matter
Benzo[a]pyrene	1.1×10^{-3}	Particulate Matter
Nickel	2.6×10^{-4}	Particulate Matter
1,3-Butadiene	1.7×10^{-4}	3.7×10^{-4}
Ethylene Oxide	8.8×10^{-5}	1.6×10^{-4}
Vinyl Chloride	7.8×10^{-5}	2.0×10^{-4}
Ethylene Dibromide	7.1×10^{-5}	5.5×10^{-4}
Carbon Tetrachloride	4.2×10^{-5}	2.6×10^{-4}
Benzene	2.9×10^{-5}	9.3×10^{-5}
Ethylene Dichloride	2.2×10^{-5}	8.9×10^{-5}
Perchloroethylene	5.9×10^{-6}	4.0×10^{-5}
Formaldehyde	6.0×10^{-6}	7.0×10^{-6}
Chloroform	5.3×10^{-6}	2.6×10^{-5}
Acetaldehyde	2.7×10^{-6}	4.8×10^{-6}
Trichloroethylene	2.0×10^{-6}	1.1×10^{-5}
Methylene Chloride	1.0×10^{-6}	3.5×10^{-6}
Asbestos	1.9×10^{-4} (per 100 fiber/m^3)	---

$\mu g/m^3$: microgram per cubic meter
ppbv: part per billion volume